

REMARKS

Claims 1 – 5, 7 – 12, 14, and 16 are currently pending. Claims 1 and 2 are the pending independent claims. In the Office Action, the Examiner withdrew all of the objections and rejections from the previous Office Action, but issued a new set of prior art rejections. Claims 1, 3, 5, and 11 – 16 were rejected as allegedly anticipated by U.S. Patent No. 7,018,658 to Platteeuw. Claims 1, 7, and 8 are rejected as allegedly obvious over the Platteeuw patent taken by itself. Finally, Claims 2, 4, and 9 – 10 are rejected as allegedly obvious over Platteeuw taken in combination with U.S. Patent No. 6,602,522 to Chen et al.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

I. The Platteeuw Anticipation Rejections.

The Examiner first argues that Claims 1, 3, 5, and 11 – 16 are anticipated by the Platteeuw reference. These rejections are not well taken.

Claim 1, and its respective dependent claims, recites a controlled release pharmaceutical formulation comprising a pellet core from which a low dosage of tamsulosin (or a pharmaceutically acceptable salt thereof) which is freely soluble in water can be released in a controlled manner independently from pH. In order to achieve this pH independent release of tamsulosin, at least one water insoluble permeable polymer is incorporated into the pellet core.

This is not disclosed in the Platteeuw reference. In fact, it is directly contrary to what is taught in Platteeuw. Platteeuw's specific goal to formulate tamsulosin in pellet cores so that the release of the tamsulosin from the cores is "dependent upon the pH" *See* Platteeuw, column 3, lines 63 – 65. To that end, Platteeuw specifies the use of an "acid resistant acrylic polymer" in the pellet core at Col. 3, lines 63 – 64 and in Claim 1. These acid resistant polymers are "not soluble in acidic aqueous medium, while they are soluble in neutral or basis aqueous medium." *See* Platteeuw, column 4, lines 59 – 60. Since the pellet cores disclosed in Platteeuw comprise an acid resistant polymer which is "not soluble in acidic aqueous medium" but is "soluble in neutral or basis aqueous medium", Platteeuw clearly does not disclose a pellet core from which a low dosage of tamsulosin, or a pharmaceutically acceptable salt thereof, which is freely soluble in water can be released in a controlled manner independently from pH.

Given this difference, the Platteeuw reference fails to disclose each and every limitation of Claims 1, 3, 5, and 11 – 16. Accordingly, for at least this reason, it is respectfully submitted that the anticipation rejections based upon Platteeuw should be withdrawn.

II. The Platteeuw Obviousness Rejections.

The Examiner also contends that Claims 1, 7, and 8 would have been from Platteeuw alone.

As noted above, however, Claims 1, 7, and 8 specify a pharmaceutical formulation with a pellet core from which a relatively low dosage of tamsulosin, or a pharmaceutically acceptable salt thereof, which is freely soluble in water, can be released in a controlled manner, independently from pH. Platteeuw is diametrically opposed to this. Platteeuw teaches the use of an “acid resistant acrylic polymer” in a pellet core configured to cause the release of tamsulosin in a manner “dependent upon the pH.” Thus, Platteeuw expressly teaches away from what is recited in Claims 1, 7, and 8.

Accordingly, for at least this reason, it is respectfully submitted that the obviousness rejections of Claims 1, 7, and 8 based upon Platteeuw are not well taken and should be withdrawn.

III. The Platteeuw with Chen Obviousness Rejections.

Finally, the Examiner contends that Claims 2, 4, and 9 – 10 would have been obvious from Platteeuw combined with Chen. It is respectfully submitted that the rejections also cannot be maintained.

Once again, Claim 1, and its dependent Claims 4, and 9 – 10, specify a pharmaceutical formulation with a pellet core from which a relatively low dosage of tamsulosin, or a pharmaceutically acceptable salt thereof, which is freely soluble in water, can be released in a controlled manner, independently from pH. Platteeuw, on the other hand, teaches the use of an “acid resistant acrylic polymer” in a pellet core so that the release of tamsulosin from the core is “dependent upon the pH.”

For a variety of reasons, the cited Chen reference cannot overcome these deficiencies in the Platteeuw patent. As an initial matter, Chen is directed to formulation for benzamidazoles, such as omeprazole. Chen does not disclose or suggest anything in regard to tamsulosin, which

differs significantly from benzamidazoles like omeprazole in both its chemical structure and its resultant physical properties, and there would have been no incentive or motivation for a person of skill working on tamsulosin formulations to look to Chen for any relevant guidance, teaching, or other ideas vis-à-vis ways of formulating tamsulosin.

Further, the dosage amounts of omeprazole disclosed in Chen do not correspond to the relatively low dosage amounts as called for in the present claims. Claim 1 recites tamsulosin in a “low dosage” form so that the tamsulosin is “freely soluble in water.” In such low dosage forms, the amount of tamsulosin is typically significantly less than one percent, by weight, of the overall core. This is demonstrated in examples in the present case. The amount of omeprazole active ingredient in Chen’s tablet cores, however, is much higher. Chen teaches that his tablet cores comprise from about 5 to about 70 wt % of the omeprazole active ingredient. More preferably, his tablet cores comprise from about 10 to about 30 wt % of the omeprazole active ingredient. Since Chen fails to teach a low dosage form of his omeprazole active ingredient, it is even more evident that Chen would not be viewed as having any teachings relevant or helpful to the person working on better ways to formulate low doses forms of tamsulosin.

Additionally, Chen’s disclosure is directed to tablet cores which are much larger than the pellet cores called for in the Applicants’ claims. Examples 1 – 5 of Chen describe the tablet cores as being from 0.2812 inches to 0.3125 inches (7.14 millimeters to 7.94 millimeters). This is far greater than the 0.5 to about 2.00 millimeters called for in regard to Applicants’ cores. Thus, Chen leads away from the claimed invention in this respect as well.

Turning to independent Claim 2, this claim also recites a pellet core comprising tamsulosin or a pharmaceutically acceptable salt thereof and at least one water-insoluble, permeable polymer. As previously discussed, the use of an insoluble permeable polymer in the pellet core allows the release of tamsulosin in a manner which is independent from pH.

However, Platteeuw does not teach the use of an insoluble permeable polymer in the pellet core. Instead, Platteeuw teaches the use of an “acid resistant acrylic polymer” which is “not soluble in acidic aqueous medium” but is “soluble in neutral or basis aqueous medium.” The Chen patent cannot cure these failings in the Platteeuw reference for the reasons noted above, namely: (1) Chen is directed to formulation of omeprazole, rather than tamsulosin; (2) Chen teaches a high dosage level for his omeprazole, rather than a low dosage level; and (3)

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Chen is directed to tablet cores which are much larger than the pellet cores of the present invention.

In light of the foregoing, the present amendment is believed to place the claims in the application in condition for allowance. Entry of the foregoing amendments and allowance of Claims 1 – 5, 7 – 12, 14, and 16 is respectfully solicited.

In the event this response is not timely filed, the Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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